IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2272
This Document Relates To: All Cases	)	Master Docket No.: 1:11-cv-05468 Judge Rebecca R. Pallmeyer

PLAINTIFFS SUPPLEMENTAL BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR SUGGESTION OF REMAND

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I. INTRODUCTION

Zimmer's argument, that the excessive forces created by the design of its Flex femoral components when in flexion beyond 120 degrees, while rocking back and forth on the tibial component, does not contribute to early loosening of the tibial component is belied by scientific evidence, biological plausibility and indeed, Zimmer's own design rationale of the NexGen Flex devices. Zimmer has seized upon this denial of physics in an attempt to create (1) an artificial distinction between failure of the femoral component because of the design flaw and failure of the knee replacement system because of the same design flaw and (2) fear of a litigation explosion. Accepting Zimmer's fallacy will not reduce any burden for this Court. In fact, it is entirely foreseeable that endorsing Zimmer's sleight of hand would only create enormous burden for district courts throughout the country and the discovery issues that would ensue in those courts, which would land right back before this Court when cross-notices of depositions and document sharing fights are sorted out. This kind of litigation duplication and inefficiency is precisely what the MDL process seeks to avoid.

With this motion for remand, Zimmer invites the Court to wade into evidentiary conclusions, both factual and scientific, based on very limited information. One of those conclusions is where and why the loosening occurred. These conclusions would have to be made without the benefit of detailed facts or expert discovery, without analysis of medical records, without analysis of X-rays and MRIs, and without the depositions of implanting and treating physicians. Under Zimmer's strained logic, if these cases were remanded to a separate district court and the revising physician testified at deposition that loosening was present on both the femoral and tibial side, the case would pinball back to the MDL. This scenario underscores the futile exercise Zimmer is attempting so early in fact discovery.

Zimmer can take the position that the JPML initially set out a limited framework for the creation of this MDL, but that is the same initial snapshot that the JPML takes at the outset of every MDL. It is the MDL judge who is uniquely qualified to expand the MDL to address efficiencies. The reality is, there is no "expansion" here. The failure of the Zimmer NexGen system correctly has been part of this MDL since day one and Zimmer's motion should be denied. In short, this is and has always been a causation argument. To wade into what is the cause of femoral or tibial loosening is far too premature, and unquestionably not the subject of a remand motion.

II. BACKGROUND

On February 10, 2012 the Zimmer entities filed a Motion for Suggestion of Remand of fourteen MDL cases and a supporting brief (Docs. 236 and 237) to which Plaintiffs filed an omnibus response in addition to several individual responses in certain cases. Zimmer filed a Reply and the Motion was set for argument at the June 1, 2012 status conference. By the time the motion for set for hearing, just four remaining cases were subject to the Motion, *Loveday, Goldberg, Messina and Krammes*. Of these, three (*Loveday, Goldberg and Messina*) involved the claim that although a NexGen Flex femoral component was involved within the NexGen system in question, the NexGen system component that demonstrated failure was the tibial component. It should be noted that in each of these cases, the original complaint specifically stated that the knee system failure was a failure of the tibial component. Nevertheless, the JPML transferred the cases and Zimmer did not oppose the transfer until this motion, approximately 6 months after the JPML order. The fourth case, Krammes, involved a recalled MIS tibial component, the Zimmer NexGen Trabecular Metal Tibia component, or Model 5954. *Krammes* was also transferred by the JPML in an order that included cases involving recalled MIS tibial components.

At the status conference on June 1, 2012, the Court asked for additional information and briefing before ruling on the Motion. In particular, the Court wanted to know what the cumulative effect that a suggestion for remand would have on the two types of cases at issue: 1) the cases alleging a defective flex femoral component with an injury of tibial loosening ("tibial loosening cases"); and 2) cases involving defective MIS 5954 tibial components.

> THE COURT: Let's talk about that as the potential result of a ruling here. How many cases -- we have got these five. How many other cases came before the panel and were rejected for MDL treatment or, alternatively, if I deny this motion, will be? We are already conservatively in the stratosphere here on numbers of cases. And that doesn't, by itself, trouble me; 400 and 1,000, it's really all the same. But the question is, are we going to be dealing with, in addition to these five, a number of other cases as to which, according to the defendants at least, additional witnesses would need to be deposed?

6/1/2012 Hearing transcript at p.24.

The Plaintiffs' Steering Committee (PSC) has investigated this issue and attempted to arrive at an internal census. The census is an estimate, because the PSC does not represent all plaintiffs and therefore could not ascertain clear data from 100% of cases filed by Plaintiffs. Nevertheless, useful data on 268 cases is available. This represents approximately 50% of filed cases to date and is a substantial sample from which well-reasoned judgments and conclusions can be made.

1. Cases with Zimmer NexGen Knees where the system failure is described as tibial loosening rather than femoral loosening.

In the Plaintiffs sample, 17.9% of cases had reported primary tibial failure with no femoral failure. Extrapolated out to the whole MDL, estimated at 550 total cases, tibial loosening cases would represent approximately 98 total cases. This means that if the court remands these cases, the total MDL would only be reduced by about 18% (to about 452 cases), but about 100 cases would be sent to dozens of districts for resolution on dozens of different discovery tracks, all with many common issues to this MDL.

2. Cases with both tibial loosening and femoral loosening.

Not discussed at the June 1, 2012 status conference was the number of cases in the MDL where the plaintiff had a Flex femoral component and both femoral and tibial loosening. From the Plaintiffs sample, 25.7% of cases have both femoral and tibial loosening. Spread over the total estimated number of filed cases, this means that approximately 141 cases have issues regarding tibial loosening, even if the court remands the cases where there is only tibial loosening. The generic discovery for all these cases would be essentially the same.

3. MIS 5954 cases

The PSC census sample demonstrates that about 6% of cases involve the recalled 5954 MIS tibial base plate. Over the entire litigation, this represents approximately 33 cases.

The question before the Court is not so much which components the Panel intended to include in its initial transfer order, but which components should be included in this MDL when applying the same standard that the Panel applies. The appropriate question to consider is

whether these cases share common questions of fact such that there would be overlap in the pretrial proceedings. If the MDL judge determines that the cases involve some common questions of fact than the cases should remain in the MDL at least until all pretrial proceedings on those common issue are completed. When all that remains in a case or a group of cases are case specific discovery or motions than at that time remand may be appropriate.

It would be premature to remand the tibial loosening cases and the 5954 cases because there is significant overlap that exists between these two groups of cases and the remaining MDL cases. For example, as demonstrated on June 1, based upon the limited discovery to date, there is significant overlap in the development teams between the 5950 and the 5954. See exhibit (ex.) A attached hereto. Prematurely remanding cases where there is such great overlap to various district courts around the country, risks inconsistent district court rulings on the same issues and can undermine the authority and proceedings of the MDL. Moreover, remanding these cases would not greatly reduce the size of this MDL. Indeed remanding all 5954 cases is an impossibility anyway, given the fact that many 5954 tibial loosening cases also include NexGen flex femoral loosening, two signature injuries that cannot be severed. Thus, it is inevitable that this court will have to include 5954 cases regardless. Why then enter a premature order on 5954 cases that will fail to create complete efficiencies anyway?

Expansion of an MDL from the original JPML Order is commonplace, especially among medical device cases where there are a family of devices or variations on a them. In turn, the common solution within MDLs involving multiple defective products is to designating cases by separate discovery schedules or having separate tracks for each device.

III. STANDARD FOR SUGGESTION OF REMAND

The power to remand a case lies solely with the JPML pursuant to 28 U.S.C. § 1407(a) and Rule 10.1(b)

> Initiation of Remand. Typically, the transferee judge recommends remand of an action, or a part of it, to the transferor court at any time by filing a suggestion of remand with the Panel. However, the Panel may remand an action or any separable claim, cross-claim, counterclaim or third-party claim within it, upon
>
> (i) the transferee court's suggestion of remand,

> (ii) the Panel's own initiative by entry of an order to show cause, a conditional remand order or other appropriate order, or
>
> (iii) motion of any party.

Judicial Panel on Multidistrict Litigation, Rule 10.0(b), 28 U.S.C.A § 1407. However, the JPML "looks to the transferee court to suggest when it should order remand." *Manual for Complex Litigation* § 20.133 (4th ed. 2004). In making the determination to remand, the Panel gives great weight and deference to the MDL Judge's suggestion that a case should be remanded.

> In considering the question of remand, the Panel has consistently given great weight to the transferee judge's determination that remand of a particular action at a particular time is appropriate because the transferee judge, after all, supervises the day-to-day pretrial proceedings. (*Citing, In re IBM Peripheral EDP Devices Antitrust Litigation,* 407 F.Supp. 254, 256 (J.P.M.L.1976)). [A]bsent a notice of suggestion of remand from the transferee judge to the Panel, any party advocating remand before the Panel bears a strong burden of persuasion.

In re Air Crash Near Nantucket Island Massachusetts, 162 F.Supp.2d 694 (J.P.M.L. 1999). The MDL Judge is in the best position to know whether a case will benefit from the coordinated litigation because of their knowledge and expertise of the litigation.

> [the transferee judge] has special insight into the question of whether further coordinated or consolidated proceedings are likely to be useful. A transferee judge's suggestion of remand to the Panel is an obvious indication that he has concluded that the game is no longer worth the candle (and, therefore, that he perceives his role under section 1407 to have ended). (Citing, *In re Brand–Name Prescription Drugs Antitrust Litig.,* 170 F.Supp.2d 1350, 1352 (J.P.M.L. 2001).

In re Light Cigarettes Marketing Sales Practices Litig., 2011 WL 6151510 at *3 (D. Maine 2011).

In making a suggestion for remand the transferee court is to consider whether remand will best serve the expeditious dispositions of the litigation. *Manual for Complex Litigation* § 20.133 (4th ed. 2004). When deciding whether to issue a suggestion for remand a MDL judge is to be guided by the standards for remand employed by the Panel. *In re Bridgestone/Firestone, Inc., et al.*, 128 F. Supp. 2d 1196, 1197 (S.D. Ind. 2001), Ex. B. When pre-trial proceedings in the MDL have not been concluded, the question of remand is discretionary. *Id*. The exercise of that discretion turns on whether the case will benefit from further coordinated proceedings as part of the MDL. *Id*. For example, when all remaining discovery in a case is case-specific, that case would be ripe for remand. *Id*. The MDL Judge must consider the totality of circumstances involved in that docket and only issue a remand when doing so will serve the convenience of the parties and witnesses and promote just and efficient conduct of the litigation. *In re Light Cigarettes Marketing Sales Practices Lit.*, 2011 WL 6151510 at *3 (D. Maine 2011).

When common questions of fact exist and the cases will benefit from pretrial proceedings such as, discovery, document production, expert testimony, Daubert, and other pretrial motions they should not be remanded to the transferor court. Once a case has been transferred the issue of whether it will benefit from the pretrial proceedings in the MDL question for the Judge; not the JPML. If Zimmer is seeking clarification of the JPML initial transfer order directly from the Panel, they can file a motion for remand directly before the Panel pursuant to Rule 10.3 of the JPML rules. *J.P.M.L.*, Rule 10.3, 28 U.S.C.A. § 1407. It is not the burden of the MDL judge to rule on the intent of a JPML transfer order in a Motion for Suggestions of Remand.

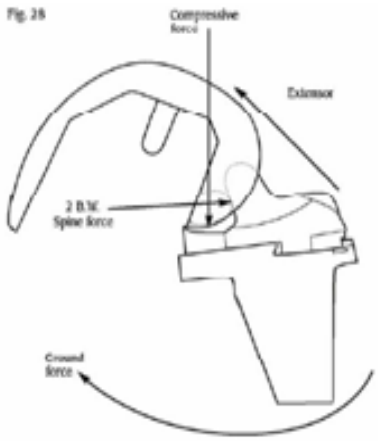
IV. ARGUMENT

1. Tibial Loosening Cases Should Remain in the MDL because they are One of the Signature Injuries of the Defective Flex Femoral Component and Share Many Common Questions of Fact and overlap with the other cases involving the defective flex femoral components.

Defendants have misconstrued Plaintiff's defective design theories among the Flex devices by stating that these three cases, *Goldberg, Loveday and Messina*, involve MDL products but the loosening of the product was not the MDL product. See Hearing Tr., 6/1/2012 at 13:17-20. At no time have the Plaintiffs limited the injuries caused by the defective Flex devices to just femoral loosening. The defective Flex device can cause loosening in any part of

the device as a result of the contact area between the femoral component and the articular surface which causes posterior edge loading on the tibial component during flexion.

These edge loading forces are at the core of Zimmer's design and testing of the flex femoral component. A constant theme throughout Zimmer's design and testing documents is concern about anterior lift-off caused by the added pressure and force that are created between the posterior femoral condyles and the posterior edge of the articular surface and tibial plate during flexion. Zimmer's own design rationale brochure for the NexGen Flex devices describes testing that was done specifically on the issue of anterior lift-off due to the forces created from the posterior edge loading at flexion. Zimmer NexGen Flex Knee Design Rationale, Z000001-000030. They tested the forces and pressure point areas that were created during flexion, which measured to be 1.4 times the body weight at the peak tilting moment of force, and the point at which anterior lift-off of the articular surface or tibial plate would occur. *Id.*, at Z000018. One of the major design changes of the Flex femoral components was the shape and thickness of the posterior condyles. See Zimmer Technical Memoerandum p.3. According to Zimmer's design rationale, this change was made in an effort to increase the contact area and minimize the point contact stresses during flexion. *Id*., at Z000019. Another concern was posterior edge loading. Zimmer's design rationale attempts to determine the minimum thickness of the tibial articular surface that would survive high-flexion activities for a lifetime of 20 years. *Id.*,at Z000021. This document also lays out articular surface spine testing, which tests the compressive force on the posterior edge of the articular surface caused by the posterior condyle in high flexion. *See* Fig.28 *infra* from Zimmer's design rationale document. *Id*., at Z000026. Zimmer had to change the design of the articular surface and the tibial plate to accommodate for these increased forces in an attempt to prevent loosening of the articular surface and the tibial plate. The design rationale states "**since the spine load will also be transmitted through the articular surface to the <u>tibial base plate</u> component**, **the testing was carried out on the component assemblies**." *Id.*, at Z000025 (emphasis added). All of these design changes were made to accommodate the high flex design and in an attempt to prevent tibial loosening during high flexion. Zimmer's position in this litigation regarding the Flex design is:



> *NexGen* Flex Femoral Components are designed to allow safe flexion without damage to the components when patients achieve flexion greater than 120 degrees.

Zimmer Technical Memorandum p. 3. Of course, Plaintiffs dispute this limited and artfully drafted statement. It has been plaintiffs' theory that the added force and pressures created as a result of the increased flexion are unsafe and cause premature loosening. This loosening can occur in any component of the device, the femoral, articular or the tibial. Not only has this been recognized in Zimmer's own documents but recent 30(b)(6) depositions have revealed that tibial failure is a concern because of the added forces created by the Flex design.

> Q. Right. My question is simply -- so, **let's take the high flex design** as an example. In a high flex design, then, the tibial baseplate in the design needs to be able to withstand the forces that are transferred to it, correct?
>
> A. Correct.
>
> **Q. And in the absence of that, one of the risks is tibial failure with the product, correct?**
>
> ***
>
> **A. Correct.**

Deposition of Brian Earl, June 6, 2012, Tr. 155:19-156:6 (emphasis added). Tibial loosening is just as much of a concern with the high Flex device as is femoral loosening. This is also seen throughout Zimmer's engineering documents for the Flex devices measuring the pressure points and forces that are created from high flexion. Additionally, peer reviewed journal articles have looked at the added forces placed on the tibial plates during high flexion activities. As stated in an article published in December 2011, in the Journal of Orthopedic Research,

> The tibial tray experiences complex loading during activities of daily living (ADL) comprising a combination of axial, anterior–posterior (AP), and medial–lateral loads, as well as flexion–extension, varus–valgus, and internal–external (IE) moments. Until recently our knowledge of the magnitude and temporal variation of these loads has been limited, but recent data from telemetric

> implants provides detailed information invaluable for pre-clinical testing.

Taylor, M.; Barrett, D.; Deffenbaugh, D.; *Influence of Loading and Activity on the Primary Stability of Cementless Tibial Trays*, Journal of Orthopedic Research 2011.[1] A similar comment is made is a 2012 article in the journal Clinical Orthopedics and Related Research:

> High magnitudes of knee flexion result in higher net quadriceps moments and joint reaction forces. Therefore, if HF-TKA implants provide increased flexion, increased stresses are incurred by the implant. Additionally, higher magnitudes of knee flexion may allow patients to perform higher load activities than what they would be able to perform if less knee flexion is present.

Ryan, D., et al., *Can a High-flexion Total Knee Arthroplasty Relieve Pain and Restore Function Without Premature Failure?*, Clin, Orthop. Relat. Res. (2012) 470:150-158. This issue is intertwined within almost every aspect of this case. If Zimmer is going to design and sell a knee replacement device that will safely accommodate flexion over 120 degrees, then the design must account for these forces. More specifically, as explained in the oral presentation, the tibial and femoral components are metal alloys which are significantly stiffer than human tissue. As a result, when force are applied in one direction to one side of the component, a force in the opposite direction is created on the other side. So downward pressure or force on the back edge of the tibial plate (posterior) created upward force on the front of the plate (anterior lift off).

Zimmer admits its concern for these forces by the testing it did on the Flex design. As stated in Zimmer's Technical Memorandum, page 6, Zimmer performed the following tests.

1. Anterior Lift-Off Testing (to test the articular surfaces in conditions that simulate deep flexion);
2. Contact Area and Conformity Analysis (to ensure that the contact area was maximized during deep flexion);

[1] Study used DePuy tibial trays but looked at the concept that the tibial tray is affected by complex forces.

3. Posterior Edge Loading Testing (to determine whether the tibial articular surface would survive the anticipated flexion activities for a lifetime of 20 years);
4. Femoral Component Strength Analysis (to verify the strength of CR Flex Femoral Component condyles);
5. Patelleofemoral Joint Compression analysis (to estimate the patellofemoral joint compression for deep flexion squatting);
6. Articular Surface Spine testing (to test the strength of the spine on the articular flexion); and
7. Posterior Lift-Off Testing (to test the fixation of the plastic articular surface).

At least 5 of these tests relate in whole or in part to the issue of force on the tibial component as articulated in the preceding paragraph, and therefore to tibial loosening. Tests 1 and 7 relate to lift off testing. Tests 2, 3, and 4 relate to forces on the tibia. Significantly, all of these tests involve testing and measurement of the entire knee replacement system, not simply a testing of the femoral component, so depositions regarding these tests would relate to both tibial and femoral failures.

Plaintiffs do not believe that the JPML intended to limit the MDL to flex cases with injuries of femoral loosening only. More importantly, such limitation would be wholly inefficient and greatly inconvenience the parties and witnesses. Whether there was tibial loosening or femoral loosening, the defective product remains the same – the flex femoral component.[2] All the depositions, document production and experts will be looking at the design of the Flex femoral components and the added forces and pressures that it creates on the device.

The JPML has appointed many MDLs involving a single defective product that can cause multiple signature injuries. When an MDL involves cases with common issues and uncommon issues the MDL judge is given leeway to formulate a pretrial program that allows pretrial proceedings with respect to any non-common issues or parties to proceed concurrently with

[2] In Flex cases where the failure was the loosening of the tibial component and the tibial component was not a 5950 or a 5954, Plaintiffs are not alleging that the tibial component is defective. Any allegations of a defective tibial component that is not a 5950 or a 5954 would be case specific and such discovery and pretrial proceedings relating to that tibial component could be handled by the transferor court at the time of remand once all the common pretrial proceedings are completed.

pretrial proceedings on common matters. *In re Multi-Piece Rim Products Liability Lit.*, 464 F.Supp. 969, 974 (J.P.M.L. 1979), attached hereto as Ex. C. Product liability actions that involve multiple signature injuries as a result of one defective product can be efficiently managed by setting up multiple discovery tracks. *See* Amended Case Management Order No. 24, *In re: Yasmin and Yaz Marketing. Sales, and Prods. Liab. Litig*, 3:09-md-02100-DRH-PMF (S.D. Ill. 2010) (MDL No. 2100), attached hereto as Ex. D. The MDL judge in *Yaz* acknowledged the variety of injuries that Yaz caused, including pulmonary embolisms, deep vein thrombosis, and gallbladder diseases. *Id.* at ¶ 5. The judge created three separate discovery tracks based on the signature injuries in order to accommodate the voluminous number of plaintiffs.[3] *Id.* at ¶ 13-15.

The judge in *Yaz* set individual tracks for each signature injury that included separate discovery deadline dates, deadlines for case specific expert disclosures and reports, completion of depositions for case specific experts, and trial dates for each of the three injuries. *See* Ex. D. The judge also set up separate bellwether tracks for the three different types of cases by having the parties designate two cases of each type of injury for a total of four cases for each injury. Amended Case Management Order No. 24, *In re: Yasmin and Yaz* at ¶ 16. From the four cases designated for each injury, each party was given two vetoes to use. *Id.* From the remaining cases after the vetoes were used, the court selected one case from each category of injury to be the first case tried for each respective injury. *Id.*

When there are multiple signature injuries stemming from a single defective product those cases must be consolidated as part of the same MDL so that all common discovery and pretrial proceedings can be completed. Once a case will no longer benefit from the consolidated proceedings, then it can be remanded and the remaining case specific discovery and motions can be handled before the transferor court.

> It is not contemplated that a Section 1407 transferee judge will necessarily complete all pretrial proceedings in all actions transferred and assigned to him by the panel, but rather that the transferee judge in his discretion will conduct the common pretrial

[3] In fact, *Yaz* has had approximately 9,415 total actions as part of the MDL, *ASR Hip* has had approximately 4,034 total actions as part of the MDL, *Pinnacle Hip* has had approximately 1,194 total actions as part of the MDL, and *Kugel Mesh* has had approximately 2,056 total actions as part of the MDL. *See* MDL Statistics Report.

> proceedings with respect to the action and any additional pretrial proceedings as he deems otherwise appropriate.

In re Light Cigarettes Marketing Sales Practices Lit., 2011 WL 6151510 at *3 (D. Maine 2011) (citing, *In re Evergreen Valley Project Litig.*, 435 F.Supp. 923, 924 (J.P.M.L. 1977)). So long as a case will benefit from the consolidated proceedings any suggestion for remand should be denied. "Remand is inappropriate when continued consolidation will conserve resources of the parties, their counsel and the judiciary." *In re Nat'l Century Fin. Enters. Inc. Fin. Invest. Litig.*, 2004 U.S. Dist. Lexis, 10605 at 9-10 (J.P.M.L. 2004) (citing *In re Heritage Bonds Litig.*, 217 F. Supp. 2d 1369, 1370 (J.P.M.L. 2002)).

In the case at hand, the purposes of centralization would be defeated if the actions involving tibial loosening were remanded. The purpose of an MDL is to avoid duplicative proceedings and provide for expediency for all parties involved. Limiting this MDL to one signature injury would create duplicative proceedings in front of another judge that would result in undue delays for the plaintiffs and create additional expenses for the courts and all the parties involved. This court is already familiar with the complex science involved in these cases, has ordered a timeline for the completion of document production and has heard argument on motions to dismiss and Zimmer's right to contact Plaintiff physicians. We have already seen that the documents produced and 30(b)(6) depositions that have been taken are directly relevant to tibial loosening. The design, engineering, testing and marketing of the Flex femoral components are all common issues of fact in both the tibial loosening and the femoral loosening cases. The issue of causation regarding the signature injuries will likely be dealt with at the *Daubert* stage. If these cases were remanded, various district courts would be hearing the same pretrial motions, which could lead to inconsistent rulings and re-litigation of the same issues that have been decided in the MDL.

Here, if necessary, separate discovery tracks could easily be setup where a track for femoral loosening and a track for tibial loosening would each exist with their own pretrial deadlines. Staggered deadlines for each signature injury could be laid out in a manageable fashion for expert report deadlines, expert depositions, bellwether selection, case specific discovery and trial dates. A remand of the tibial loosening cases would only decrease the MDL by about 14%. More concerning is the fact that there are many cases that involve both femoral loosening and tibial loosening. Not discussed at the June 1, 2012 status conference was the

number of Flex cases in the MDL where the plaintiff had both femoral and tibial loosening. From the PSC sample, 25.7% of cases have both femoral and tibial loosening. Spread over the total estimated number of filed cases, this means that approximately 141 cases have issues regarding tibial loosening. Cases involving both signature injuries, tibial and femoral loosening, would greatly benefit from the tibial loosening only cases remaining in the MDL since such injuries could not be severed. By remanding tibial loosening cases, there could very likely be inconsistent rulings by various district courts that could greatly complicate the cases involving both tibial and femoral loosening.

By maintaining separate discovery tracks and trials for the different injuries it ensures consistency and most importantly promotes efficient and expeditious resolution of all these cases. To remand all tibial loosening cases would be egregious error and would only burden all parties involved without providing any benefit.

a. The 5954 MIS Tibial Component is Sufficiently Similar to the 5950 MIS Tibial Component and should be Included in the MDL because they share Common questions of Fact

The actions that involve the 5954 Tibial Component should not be remanded to their respective transferor courts. The statutory test for multidistrict litigation is if the cases share "common questions of fact." There are many common questions of fact between the 5950 and the 5954 such that both components should be included in this MDL.

The JPML transfer order for this MDL references the JPML order in the Pinnacle Hip MDL. *See* 802 F. Supp. 2d. 1374, 1377 (J.P.M.L. 2011). In *Pinnacle*, some of the plaintiffs requested to limit the scope of the MDL to a specific configuration of the hip implant that was at issue, but the JPML refused to limit the MDL's scope. *In re: DePuy Orthopaedics, Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358, 1360 (J.P.M.L. 2011). The JPML reasoned that it was too early in the litigation to limit the MDL's scope. *Id.* The JPML further reasoned that the transferee judge could "employ any number of pretrial techniques—such as establishing separate discovery or motion tracks—to efficiently manage" the litigation if the transferee judge decided to included the multiple configurations of the hip replacement system. *Id.* The JPML was not concerned that the MDL might include multiple products, which failed for different reasons, as it had full faith "in the transferee judge's ability to streamline pretrial proceedings in all actions, while concomitantly directing the appropriate resolution of all claims." *Id.*

Moreover, centralization among claims involving multiple products from a single manufacturer are often consolidated in one MDL in order to properly effectuate the purpose of 28 U.S.C. § 1407. *See generally In re: Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F. Supp. 2d 1371, 1372 (J.P.M.: 2007), attached hereto as Ex. E. In *Kugel Mesh*, the thirteen actions that were part of the MDL all involved various models of hernia patches that were manufactured and sold by various defendants. *Id.* Even though the models of the hernia patches were different and multiple defendants were involved, the JPML still included all thirteen of the actions in the MDL because "all actions can [] be expected to share factual questions." *Id.* The related factual questions involved the "design, manufacture, safety, testing, marketing, and performance" of the hernia patches. *Id.* The JPML stated that "transfer under Section 1407 does not require complete identity or even a majority of common factual or legal issues as a prerequisite to transfer." *Id.* at 1373-74. Although multiple products were involved, centralization of all the actions was still "necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary." *Id.* at 1372.

Furthermore, when multiple products share common questions of fact, consolidation serves the best interest of all parties. *See In re: Celotex Corporation Technifoam Prods. Liab. Litig.*, 424 F. Supp. 1077 (J.P.M.L. 1977). In *Celotex*, only actions that involved Celotex Corporation's "Technifoam" insulation were transferred for consolidated pretrial proceedings. *Id.* However, the JPML allowed a different type of insulating foam that was manufactured by a different corporation to be transferred to the *Celotex* MDL because the other insulating foam shared enough common questions of fact with Celotex's insulating foam. The JPML found that transfer of these new actions to the Celotex MDL would "best serve the convienence of the parties and promote the just and efficient conduct of the litigation. *Id.* at 1. Although the defendants tried to argue that the products were unrelated to each other, the JPML "found these arguments unpersuasive," and instead transferred these new actions which "shared common questions of fact with the actions in the transferee district" and was thus "necessary in order to eliminate the possibility of duplicative discovery and prevent inconsistent pretrial rulings." *Id.* at 1-3.

Here, centralization of all actions involving both the 5950 and the 5954[4] tibial components is necessary. Like in *Kugel Mesh*, where multiple products were all centralized under the same MDL, the 5950 and 5954 tibial components should be centralized because they share common questions of fact. Both products were approved through the 510(k) process and share some of the same predicate devices. The design teams for both products are substantially similar. This means that custodial files and depositions of these individuals, the 30(b)(6) MIS deposition[5] and individual custodian depositions, will involve a lot of common overlap. These two tibial components are variations of each other, but both are used in MIS surgeries as part of the NexGen line, both are used with the NexGen Flex femoral component, and are manufactured by the same company. The 5950 and the 5954 share many common questions of fact relating to their design, testing, marking for use in MIS procedures, the complexities and challenges in MIS procedures, and Zimmer's training and instruction to surgeons on MIS techniques. Since both products have very similar design teams, the discovery process for the 5954 actions will be virtually identical to the discovery process of the 5950 tibial component actions. When depositions of individuals who were on both design teams are taken, Zimmer will only have to produce that witness once and Plaintiffs will be permitted to question on the issues of the 5950 and the 5954, which will greatly conserve resources since many of the issues overlap. Although there may be some documents or depositions that will only be applicable to one of the components, it will be minimal. At the appropriate time, when only case specific discovery is remaining, this court may decide to remand the 5954 cases, but to do so now would be premature.

According to the Plaintiffs about 6% of the cases in the MDL involve recalled 5954 tibial components. Of those approximately 33 cases, about 14 of them also involve a Flex femoral component. Although the *Krammes* case does not involve a Flex femoral component, its important to recognize that many of these case do. Thus, this court is inevitably going to have cases alleging both a defective flex and defective 5954 tibial. For purposes of efficiency of

[4] Although Zimmer is in a better position to know how many of these cases are currently in the MDL, Plaintiffs' survey shows that about 6% of cases involve the recalled 5954 MIS tibial base plate. Over the entire litigation, this represents approximately 33 cases.

[5] As a result of scheduling conflicts the MIS 30(b)(6) deposition has not taken place and will not take place prior to the July 13, 2012 status conference.

proceedings, concurrent discovery on the common questions of fact that exist between the 5950 and the 5954 should be permitted. By allowing the 5954 cases to remain in the MDL it will conserve the parties' resources when we get to expert discovery, as any expert retained for the 5950 will likely also be able to provide expert testimony on the 5954.

It is for these same reasons that the JPML has ordered the transfer of different products into already existing MDLs. In *In re Bridgestone/Firestone, Inc., Tires Products Liability Litig.*, 151 F.Supp.2d 1381 (J.P.M.L. 2001), see Ex. B, the JPML ordered the transfer of four cases involving two different models of Firestone tires that were not already part of the existing MDL. The JPML reasoned that relevant discovery, including expert testimony, will overlap substantially and that the cases involved common questions of fact with the previously transferred cases, including whether Firestone tires are defective and whether Firestone had knowledge of such defects. *Id*. at 1382. In applying the same reasoning as the JPML, various MDL courts have permitted cases involving additional products other than that which was included in the JPML's original transfer order. For instance, in the Hormone Replacement ("HRT") MDL the original transfer order was for six actions brought against Wyeth by individuals injured by the drug, Prempro. See *In re Prempro Products Liability Litig.*, 254 F.Supp. 2d 1366, 1367 (J.P.M.L. 2003). Over time, the HRT MDL grew to include many other HRT drugs, including others manufactured by Wyeth and some manufactured by other companies. See, generally, *In re: Prempro Products Liability Litig.*, 554 F. Supp. 2d 871 (E.D. Ark. 2009)(unrelated opinion regarding a J.N.O.V involving a MDL case involving Premarin, Prempro and Provera); See, also, *In re: Prempro Products Liability Litig.*, 2006 U.S. Lexis 78659 (E.D. Ark. 2009)(opinion regarding a Motion to Dismiss for unrelated reasons where the products at issue were Provera and Ogen and the defendants were Pfizer and Abbott Laboratories Inc.). The HRT MDL grew at the discretion of the MDL judge who determined over time that the other actions involved common questions of fact such that they would benefit from centralization.

If the two tibial components were to be separated into two separate MDL's, the intent of Section 1407 would have to be overlooked because the result of remanding one class of tibial components would result in duplicative discovery, inconsistent pretrial rulings, and would waste the resources of all parties involved. It is not appropriate to transfer the 5954 tibial cases at this time because they do share common questions of fact and should remain in the MDL until there

will be no benefit derived from the common pretrial proceedings and all that remains is case specific.

2. A Decision on Remand of the 5954 Cases is Premature as Discovery Requested by the Court has not been completed.

At the June 1, 2012 status conference, the Court said at pages 37-8:

> The Court: I guess I would like to wait for some of that initial discovery and whatever disputes pop up when you start asking these people questions and they say, 5954, sure, it's the same team, but we were looking at an entirely different problem. We have the same team because we are the experts in this field. That doesn't mean we are always doing the same thing. We were -- there is a reason that it's a different model number, and that reason relates to why it is that these people with a 5954 don't belong in this lawsuit.
> I guess I would like to wait for a little bit of discovery on that issue, because at this point it seems to me that the defendants are correct that, look, we have got a huge MDL as it is right now; why do we want to make it any larger? You are saying, this doesn't really make it any larger; these people belong here in the first place.
> MR. RONCA: All it does is make litigation elsewhere larger.
> THE COURT: And I am very sensitive to that.
> First of all, your argument that if they genuinely want to have these people deposed not once, twice, 20, 30, 40 times, you are right, the motivation cannot be efficiency.
> ……
> I guess I would like to see things evolve a little bit more before I make a final decision on this.

Unfortunately because of scheduling difficulties, the initial discovery on these points has not occurred and will not occur before the July 13 status conference. Therefore, we cannot supply the answers to these very important questions until the next status conference. Plaintiffs maintain that there is substantial discovery crossover between the MIS 5950 cases and the MIS 5954 cases. Further, Plaintiffs say that the MDL order only refer to “MIS Tibial” and therefore is not limited to the MIS 5950. Defendants say there is little crossover and little efficiency to be gained by keeping the 5954 cases in the MDL. As the Court wisely pointed out, the answers to

these questions will come in some initial discovery. Plaintiffs requests the Court to wait for this discovery before making the decision based upon very limited and disputed facts.

V. CONCLUSION

In applying the same reasoning as the JPML, the court should deny Zimmer's Motion for Suggestion of Remand because the tibial loosening cases share common questions of fact with the other cases alleging defective Flex design and the 5954 MIS tibial cases share common questions of fact with the 5950 MIS tibial cases.

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Respectfully submitted,

ANAPOL SCHWARTZ

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CERTIFICATE OF SERVICE

I certify that on June 27, 2012, the foregoing Plaintiffs Supplemental Brief In Opposition To Defendants' Motion For Suggestion Of Remand was filed electronically. Parties may access this filing through the Court's system.

/s/ James R. Ronca